

public display in the Dockets Management Branch under Docket No. 95S-0135. Updated information related to patents on animal drug products will be placed on public display in the Dockets Management Branch under Docket No. 95S-0126. Updated patent information for human drug products will be published in the monthly supplements to "Approved Drug Products with Therapeutic Equivalence Evaluations" (the Orange Book) and updated patent information for animal drug products will be published in the monthly supplements to "FDA Approved Animal Drug Products" (the Green Book) after June 8, 1995.

### III. Amended Patent Certifications

Abbreviated new drug applications (ANDA's), abbreviated new animal drug applications (ANADA's), and applications provided for in section 505(b)(2) of the act (505(b)(2) applications) pending before the agency on June 8, 1995, including such applications that may have received tentative approval letters, must be amended to respond to the URAA-extended patent expiration dates, if information on the new expiration dates is submitted to the agency by the NDA or NADA holder in a timely manner. ANDA's, ANADA's, and 505(b)(2) applications submitted after June 8, 1995, likewise must provide patent certifications with respect to the URAA-extended patent expiration dates. After June 8, 1995, FDA will not approve any application that does not contain a correct certification with respect to a URAA-extended patent expiration date that was submitted in a timely manner to the agency. The agency expects that an applicant that wishes to market a drug under an approved ANDA, ANADA, or 505(b)(2) application before the expiration of a URAA-extended patent, for which information was submitted to FDA in a timely manner, will file a paragraph IV certification with respect to that patent (See sections 505(b)(2)(A), (j)(2)(A)(vii), and 512(n)(1)(H) of the act.)

Amended patent certification statements for abbreviated new drug applications (ANDA's) and 505(b)(2) applications reviewed by the Office of Generic Drugs should be sent to the Office of Generic Drugs, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Amended patent certification statements for 505(b)(2) applications reviewed by the new drug reviewing divisions within CDER should be sent to the appropriate review division. Amended patent certification statements

pertaining to animal drug products should be sent to the Document Control Unit, Center for Veterinary Medicine (HFV-199), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Amended patent certification statements pertaining to biological products should be sent to the Document Control Center, Center for Biologics Evaluation and Research (HFM-99), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448.

Dated: June 2, 1995.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 95-14060 Filed 6-5-95; 2:29 pm]

BILLING CODE 4160-01-F

### [Docket No. 95M-0119]

#### **Chartex International plc; Premarket Approval of Femidom® Female Condom**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Chartex International plc, London, U.K., for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Femidom® Female Condom. The device is to be manufactured under an agreement with Wisconsin Pharmacal Co., Inc., Jackson, WI, which has authorized Chartex International plc to incorporate information contained in its approved premarket approval application for the Reality™ Female Condom (P910064). FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of April 14, 1995, of the approval of the application.

**DATES:** Petitions for administrative review by July 10, 1995.

**ADDRESSES:** Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Colin M. Pollard, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180.

**SUPPLEMENTARY INFORMATION:** On September 30, 1994, Chartex International plc, London, U.K., submitted to CDRH an application for

premarket approval of the Femidom® Female Condom. The device is an intravaginal barrier device and is indicated for use to help prevent pregnancy and sexually transmitted diseases (STD's), including the human immunodeficiency virus (HIV) infection during vaginal intercourse. The application includes authorization from Wisconsin Pharmacal Co., Inc., Jackson, WI, 53037, to incorporate information contained in its approved premarket approval application for the Reality™ Female Condom (P910064). In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Obstetrics and Gynecology Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On April 14, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

#### **Opportunity for Administrative Review**

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be

used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before July 10, 1995, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: May 26, 1995.

**Joseph A. Levitt,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

[FR Doc. 95-14059 Filed 6-7-95; 8:45 am]

BILLING CODE 4160-01-F

## Substance Abuse and Mental Health Services Administration (SAMHSA)

### Competitive Supplements for Integrated Children and Family Services

**AGENCY:** Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

**ACTION:** Notice of availability of supplemental funds for certain programs of the Center for Mental Health Services (CMHS), Center for Substance Abuse Prevention (CSAP) and Center for Substance Abuse Treatment (CSAT).

**SUMMARY:** This notice informs the public that SAMHSA is making available approximately \$2-3 million in Fiscal Year 1995 for up to 10 supplemental awards to existing grantees who have a minimum of 3 years of Federal grant support remaining as of September 1995, as reflected on the current Notice of Grant Award. Funds are being provided to support 3 year supplemental projects designed to implement and evaluate the

effectiveness of integrated service delivery approaches for families with children from birth to 7 years of age, who are affected by alcohol, drug abuse and/or mental health disorders or who are at risk for such disorders.

Eligibility is limited to grantees with 3 years remaining in the following SAMHSA programs in order to be able to evaluate the effects of funding such integrated approaches in a known, well-defined project where the various strengths and other grantee characteristics have already been generally identified. Thus, most of the variables affecting performance are known so that the direct effects of the supplemental funding can be better measured than would be possible in an untested environment. This control in supplementing a variety of different programs allows the maximum insight to be obtained with the limited resources available. The grantees will need to have 3 years remaining since we do not anticipate having measurable results to evaluate in a shorter period.

Eligible program	CFDA No.	Statutory authority PHS Act
CMHS:		
Cooperative Agreements for ACCESS—Demonstration Projects for Homeless Persons with Severe Mental Illness.	93.125	520A
Grants for Comprehensive Community Mental Health Services for Children and Adolescents with Serious Emotional Disturbances.	93.104	561, Pt. E, Title V
CSAP:		
The Community Prevention Coalitions Demonstration Grant Program .....	93.194	501(d)(5); 516
Substance Abuse Prevention Demonstration Grants for High Risk Youth Populations (excluding Module D-Replications).	93.144	517
CSAT:		
Services Grant Program for Residential Treatment for Pregnant and Postpartum Women .....	93.101	508
Demonstration Grant Program for Residential Treatment for Women and Their Children .....	93.102	510
Cooperative Agreements for Substance Abuse Treatment and Recovery Systems for Rural, Remote and Culturally Distinct Populations.	93.122	510(b)(1)

The receipt date for applications is July 25, 1995. The application review and award process will be handled in an expedited manner. Applications will be evaluated for technical merit by a panel of expert non-Federal and Federal reviewers. Awards will be made on the basis of the award criteria set forth in the supplemental guidelines subject to the availability of funds. Awards will be made no later than September 30, 1995.

#### FOR FURTHER INFORMATION CONTACT:

Questions concerning program issues should be directed to SAMHSA Project Officers for the existing SAMHSA grants. Questions concerning grants management issues should be directed to SAMHSA Grants Management Specialists for the existing SAMHSA grants.

Dated: June 2, 1995.

**Richard Kopanda,**

*Acting Executive Officer, SAMHSA.*

[FR Doc. 95-13985 Filed 6-7-95; 8:45 am]

BILLING CODE 4162-20-P

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

### Office of the Assistant Secretary for Housing—Federal Housing Commissioner

[Docket No. N-95-3909; FR-3904-C-02]

### Notice of Fund Availability (NOFA) for Supportive Housing for the Elderly; Correction

**AGENCY:** Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

**ACTION:** Notice of fund availability for Fiscal Year (FY) 1995; Correction.

**SUMMARY:** This notice corrects the NOFA for Supportive Housing for the Elderly, published in the **Federal**